

THIS ISSUE

Testing for and Treatment of Bloodborne Pathogens

TO:

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Purpose:

The purpose of this provider bulletin is to communicate to providers which of the tests and treatments that are used for Hepatitis B and C and HIV are covered services for workers' compensation and crime victims' claims. The billing codes and policies described in this Provider Bulletin apply to State Fund, Self-Insured, and crime victims' claims and are currently in effect.

In addition, background information on these bloodborne pathogens is provided as an appendix to this document.

This Provider Bulletin replaces Provider Bulletin 94-17.

| Table of Contents | Page |
|---|----------|
| I. What to do if an Exposure Incident Occurs at Work | |
| ♦ Industrial Insurance Act..... | 2 |
| ♦ Filing a Workers' Compensation Claim..... | 2 |
| ♦ Covered Testing Protocol(s)..... | 2 |
| ♦ Post-exposure Prophylaxis for HBV..... | 6 |
| ♦ Post-exposure for Prophylaxis for HIV..... | 6 |
| II. Covered Bloodborne Pathogen Treatment Regimens | |
| ♦ Hepatitis B (HBV)..... | 6 |
| ♦ Hepatitis C (HCV)..... | 6 |
| ♦ Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Virus (AIDS) | 7 |
| III. Billing Codes..... | 7 |
| IV. Appendix | |
| ♦ Background Information on Bloodborne Pathogens..... | 8 |
| ♦ Record Keeping/Confidentiality..... | 9 |
| ♦ Additional Resources..... | 10 |

I. What to do if an Exposure Incident Occurs at Work

Industrial Insurance Act

The Industrial Insurance Act, specifically RCW 51.36.010 and WAC 296-20-03005, allows the department or self-insured employer to pay for post-exposure treatment whenever an **injury** (such as a needle stick or laceration) occurs and there is a potential exposure to an infectious disease.

The Industrial Insurance Act also allows for post-exposure treatment in cases in which a work-related activity has resulted in probable **exposure** of the worker to a potential infectious occupational disease, but with no injury. In these cases, there must be a documented or probable work-related exposure in an occupation where there is a greater likelihood of contracting the disease on the job and there must be an employee/employer relationship. Authorization of such treatment does not bind the department or self-insured employer in the allowance of a claim that the worker contracted the related occupational disease.

Filing a Workers' Compensation Claim

The exposed worker must apply for benefits (e.g., submit the appropriate accident report form) before the insurer can pay for testing and treatment protocols.

Per RCW 51.28.050, industrial injury claims, such as needle sticks, must be filed within one year after the day upon which the injury occurred. RCW 51.28.055 states that a claim for an occupational disease must be filed within two years following the date a worker receives written notice from a physician that an occupational disease exists.

If an injury occurred, such as a needle stick, and the claim was allowed and then closed, the worker must file a reopening application if he or she later contracts an infectious disease from the injury.

When a claim is filed for probable exposure, where there is no evidence of an injury or occupational disease, the claim will be rejected. However, post exposure treatment will be authorized if there was a greater likelihood of the worker contracting the disease on the job. If subsequent testing shows that the worker has contracted an infectious disease from the occupational exposure, the worker must file a new claim for contraction of that occupational disease.

Covered Testing Protocol(s)

Seroconversion (the change of a serologic test from negative to positive, indicating the development of antibodies in response to infection or immunization) can take months to occur for the various blood borne diseases. Testing for Hepatitis B, C, and HIV should be done at the time of exposure and at 3, 6, and 12 months post exposure.

Testing at the time of the exposure helps determine if the exposed worker was positive or negative prior to the exposure. The department or self-insured employer will not pay for source testing as part of the workers' compensation claim. For rules that apply to employers, including when it is an employer's responsibility to pay for source testing, see <http://www.lni.wa.gov/wisha/p-ts/BBPathogens/>.

The following is a list of tests that are covered services by the Department of Labor and Industries.

Hepatitis B (HBV)

The three following blood tests are the only way to determine if one is currently infected with, has recovered from, are a chronic carrier of, or are susceptible to HBV:

| <u>Test</u> | <u>Application</u> | <u>Comments</u> |
|--|---|---|
| HbsAg (hepatitis B surface antigen) | <ul style="list-style-type: none"> Indicates current and/or chronic infection. | <ul style="list-style-type: none"> HbsAg is usually the first detectable marker of HBV infection. |
| Anti-HBc or HBc-Ab (antibody to hepatitis B core antigen) | <ul style="list-style-type: none"> Indicates existing or past infection. | <ul style="list-style-type: none"> High incidence of false-positives. |
| Anti-HBs or HBs-Ab (antibody to hepatitis B surface antigen) | <ul style="list-style-type: none"> Detects immunity to HBV. | <ul style="list-style-type: none"> A “positive” or “reactive” result means patient is immune to HBV either as a result of having had the disease prior or from having had the HBV vaccine. |

Hepatitis C (HCV)

Anti-HCV can be detected in 80% of patients within 15 weeks after exposure, in $\geq 90\%$ within 5 months after exposure and in $\geq 97\%$ by 6 months after exposure. The following tests detect HCV antibody (anti-HCV) in the blood, but do not distinguish between acute, chronic, or resolved infections:

| <u>Test</u> | <u>Application</u> | <u>Comments</u> |
|--|--|--|
| Enzyme Immunoassay (EIA) | <ul style="list-style-type: none"> Indicates past or present infection, but does not differentiate between acute, chronic, or resolved infection. | <ul style="list-style-type: none"> All positive EIA results should be verified with a supplemental assay. |
| Recombinant Immunoblot Assay (RIBA) | <ul style="list-style-type: none"> Supplemental assay used when a positive EIA is reported. | <ul style="list-style-type: none"> Results might be reported as positive, negative, or indeterminate. |
| Strip Immunoblot Assay (SIA) | <ul style="list-style-type: none"> Able to detect one more type of antibody than EIA and RIBA tests. | <ul style="list-style-type: none"> Supplemental assay used to test blood specimens that have already tested repeatedly reactive on above screening tests. |

Qualitative HCV RNA testing using reverse transcriptase polymerase chain reaction (RT-PCR) is the only way to determine whether or not one has active HCV. RT-PCR is able to detect HCV RNA as early as 1-2 weeks following exposure and are used to confirm a positive or indeterminate anti-body test result. The following summarizes currently available HCV RNA tests:

| <u>Test</u> | <u>Application</u> | <u>Comments</u> |
|---|--|--|
| Qualitative reverse transcriptase polymerase chain reaction (RT-PCR) | <ul style="list-style-type: none"> • Detects presence of HCV RNA. • Monitors antiviral therapy response. | <ul style="list-style-type: none"> • Able to detect virus 1-2 weeks post-exposure. • High sensitivity. |
| <i>The following tests are covered services once HCV is an accepted condition on a claim:</i> | | |
| Quantitative reverse transcriptase polymerase chain reaction (RT-PCR) | <ul style="list-style-type: none"> • Determines concentration of HCV RNA. • Used to assess likelihood of response to antiviral therapy. | <ul style="list-style-type: none"> • Liver biopsy is the only way to determine the extent of hepatic injury. |
| Branched-chain DNA (bDNA) | <ul style="list-style-type: none"> • Determines concentration of HCV RNA. • Used to assess likelihood of response to antiviral therapy. | <ul style="list-style-type: none"> • Liver biopsy is the only way to determine the extent of hepatic injury. • Less sensitive than PCR tests. |
| Genotyping Several methodologies available (e.g., hybridization, sequencing) Note: Genotyping only needs to be performed once. | <ul style="list-style-type: none"> • Isolates HCV by genetic differences, into specific genotype. • Used to assess likelihood of antiviral therapy response. | <ul style="list-style-type: none"> • Identifying genotype may help determine potential response to antiviral therapy. • Treatment length dependent on genotype (i.e. 6 months for genotypes 2&3, 12 months for genotype 1) |
| Liver Biopsy | <ul style="list-style-type: none"> • Assessment of liver inflammation and fibrosis. | <ul style="list-style-type: none"> • Allows health care provider predict prognosis and guide treatment decisions. |

HIV

Two blood tests are needed to verify the presence of HIV in blood, a Rapid HIV or Enzyme Immunoassay test, and a Western Blot test to confirm a seropositive status. The following tests are used to determine the presence of HIV in blood:

| <u>Test</u> | <u>Application</u> | <u>Comments</u> |
|---|--|--|
| Rapid HIV Test | <ul style="list-style-type: none">• Detects HIV antibody in blood, usually in 5 to 30 minutes. | <ul style="list-style-type: none">• Quick and is considered as reliable as other standardized tests. |
| Enzyme Immunoassay (EIA) Test | <ul style="list-style-type: none">• Standard screening test used to detect HIV antibody in blood. | <ul style="list-style-type: none">• This test should be used with a confirmatory test.• Also known as the ELISA test. |
| Western Blot Test | <ul style="list-style-type: none">• Standard test used to confirm the presence of HIV antibodies in blood. | <ul style="list-style-type: none">• Use to confirm results either Rapid HIV or EIA test. |
| Immunofluorescent Antibody | <ul style="list-style-type: none">• Some laboratories use instead of Western Blot to confirm presence of HIV antibodies in blood. | <ul style="list-style-type: none">• If this testing modality is used, negative or indeterminate results should be followed by a Western Blot test. |
| <i>The following tests are covered services once HIV is an accepted condition on a claim:</i> | | |
| HIV Antiretroviral Drug Resistance Testing | <ul style="list-style-type: none">• Phenotypic testing measures viral replication in the presence of antiviral drugs.• Genotypic testing used to detect gene mutations associated with resistance to therapy. | <ul style="list-style-type: none">• Correlation between viral drug resistance and response to therapy.• Meant to compliment rather than replace clinical decision-making regarding antiretroviral drug regimen. |
| Blood Count, Kidney, and Liver Function Tests | <ul style="list-style-type: none">• Used to predict/determine drug toxicity. | <ul style="list-style-type: none">• Tests should be completed before treatment, 2 weeks after starting treatment, and then periodically. |
| CD4 Count | <ul style="list-style-type: none">• Blood test that counts the number of CD4 white blood cells. | <ul style="list-style-type: none">• Used to assess disease status and response to therapy.• Lower levels of white blood cells might signify disease progression. |
| Viral Load Testing | <ul style="list-style-type: none">• Amplifies and quantifies HIV (e.g. RT-PCR). | <ul style="list-style-type: none">• Used to monitor disease progression and for assessing response to therapy. |

Post-exposure Prophylaxis for HBV

Depending on the exposed individual's baseline serologic data and medical history, treatment with hepatitis B immune globulin (HBIG) and the hepatitis B vaccine may be appropriate. HBIG should be given as close to the time of exposure as possible; its effectiveness if administered more than 14 days after exposure will be greatly diminished or absent.

Post-exposure Prophylaxis for HIV

Post-exposure prophylaxis is given after occupational exposure to HIV in order to reduce the risk for HIV transmission. Such treatment should be started as soon as possible after the exposure.

When a possible exposure to HIV occurs, the Department or self-insured employer may pay for chemoprophylaxis treatment in accordance with the most recent Public Health Services (PHS) Guidelines. Prior authorization is not required. The decision on which specific drug protocol to use within the PHS Guidelines, after occupational exposure, is left to the treating physician as many factors unique to the patient and exposure must be considered. A link to the CDC guidelines is included in the resources section of this bulletin.

When chemoprophylaxis is administered, the insurer will pay for drug-toxicity monitoring. This includes complete blood count, renal, and hepatic chemical function tests at baseline and periodically during drug treatment. Further tests may be indicated if toxicity is found.

II. Covered Bloodborne Pathogen Treatment Regimens

Chronic Hepatitis B (HBV)

There are currently two available treatment options for chronic hepatitis B.

1. Interferon alfa-2b, and
2. Lamivudine

Hepatitis C (HCV)

There are two treatment regimens that are covered services for an individual with **acute** Hepatitis C:

1. Mono Therapy
Mono therapy with interferon alfa should be administered for patients with a diagnosis of active hepatitis C who are at the greatest risk for progression to cirrhosis.
2. Combination Therapy
Rebetron™ Combination Therapy (interferon alfa-2B + ribavirin), is FDA approved for treating HCV in patients who have not received prior treatment with interferon and in patients who have failed previous interferon therapy for HCV.

Note: Patients who have not responded to the combination therapy by week 24 are unlikely to benefit from further treatment.

Because the treatment available for acute HCV is limited in terms of effectiveness, HCV infection may eventually lead to liver failure. For state fund claims, requests for liver transplantation must go through inpatient utilization review.

HIV/AIDS

Covered services are limited to those within the most recent guidelines issued by the HIV/AIDS Treatment Information Service (ATIS). ATIS provides information about federally approved treatment guidelines for HIV and AIDS. A link to these guidelines is included in the resources section of this provider bulletin.

Treatment for HIV infection varies according to patient and severity of the disease. Like the treatment of most chronic diseases, antiretroviral regimens are complex, have major side effects, pose difficulty with compliance, and carry serious potential consequences with the risk of resistance from non-adherence to the drug regimen or suboptimal levels of antiretroviral agents.

A number of drugs are available to help treat opportunistic infections to which people with HIV are especially prone. For example, these drugs may include but are not limited to ganciclovir for cytomegalovirus infections, fluconazole for yeast and other fungal infections, and trimethoprim/ sulfamethoxazole (TMP/SMX) or pentamidine for pneumocystis carinii pneumonia (PCP).

III. Billing Codes

| <i>Diagnostic Test/Procedure:</i> | <i>2001 CPT Code:</i> |
|--|---|
| Hepatitis B Surface Antigen (HBsAg) | 87340 |
| Hepatitis B Core Antibody (HBcAb) | 86704 |
| Hepatitis B Surface Antibody (HBsAb) | 86706 |
| Hepatitis C Antibody (e.g. EIA) | 86803 |
| Hepatitis C Antibody Confirmatory Test (e.g. RIBA, SIA) | 86804 |
| Hepatitis C, Amplified Probe Technique (e.g. Qualitative RT-PCR) | 87521 |
| Hepatitis C Quantification (e.g. Quantitative RT-PCR, bDNA) | 87522 |
| Hepatitis C Genotyping | 83890, 83894, 83896, 83898, 83902, 83912 |
| Liver Biopsy | 47100 |
| HIV-1 Antibody Testing | 86701 |
| HIV-1 Enzyme Immunoassay (EIA) | 87390 |
| HIV Confirmatory Test (e.g. Western Blot, Immunofluorescent) | 86689 |
| HIV Antiretroviral Resistance Testing (Genotypic) | 87901 |
| HIV Antiretroviral Resistance Testing (Phenotypic) | 87903 (first ten drugs) 87904 (each additional drug, up to five) |

| <i>Treatment Related Procedures:</i> | <i>2001 CPT Code:</i> |
|---|------------------------------|
| Office or Other Outpatient Visits (evaluation and management) | 99201-99215 |
| Hospital Observation Services | 99217-99220 |
| Therapeutic, Prophylactic, or Diagnostic Injections | 90782-90799 |
| Hepatitis B Vaccine | 90746 (adult) |
| Hepatitis B Immune Globulin (HBIG) | 90371 |
| HIV Exposure Initial Treatment Kit (prophylaxis) | 3060A (L&I department code) |
| Hepatic Function Panel | 80076 |
| Kidney Function Test | 78725 |
| CD4 Count | 86360 |
| HIV Viral Load Testing | 87536 |

IV. APPENDIX: ADDITIONAL INFORMATION ON BLOODBORNE PATHOGENS

Background Information on Bloodborne Pathogens

Bloodborne pathogens are microorganisms present in human blood or other potentially infectious material with the ability to infect and cause disease in humans when an exposure incident occurs. An exposure incident refers to a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral (i.e. piercing of mucus membranes or skin) contact with blood or other potentially infectious material. Nationally, it is estimated that between 590,000-800,000 needlestick injuries occur annually.¹ Below is a summary of medical information for each of the bloodborne diseases referenced in this bulletin.

Hepatitis B

Hepatitis B is an inflammatory disease of the liver caused by the hepatitis B virus (HBV). Hepatitis B is transmitted through direct contact with bodily fluids containing HBV, such as blood or blood products, and other potentially infectious material. The onset of symptoms after exposure to HBV varies from six weeks to six months. Over half of those infected are asymptomatic.

HBV infection can cause acute illness that leads to loss of appetite; tiredness; pain in muscles, joints, or stomach; diarrhea or vomiting; and jaundice. HBV can also cause chronic infection that leads to liver damage (cirrhosis), liver cancer, and death.

Approximately 90-95% of adults will develop antibodies against the disease, clear the virus from their bodies, and recover within 6 months. Five to ten percent of adults will never develop antibodies to the virus, will become chronic hepatitis B carriers, and will be at an increased risk of developing liver disease such as cirrhosis or liver cancer. Post exposure treatment is available to those exposed to HBV.

¹ Occupational Safety & Health Administration, U.S. Department of Labor. *Directive CPL 2-2.44D: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*. November 5, 1999, P 14.

Hepatitis C

Hepatitis C is an inflammatory disease of the liver caused by the hepatitis C virus (HCV). Hepatitis C is transmitted through direct contact with bodily fluids containing HCV, such as blood or blood products, and other potentially infectious material. Blood transfusion, which accounted for a substantial portion of HCV infections acquired greater than 10 years ago, rarely accounts for recently acquired infections.

Most individuals who are infected with HCV do not have symptoms. If symptoms are present, they may be very mild and flu-like including nausea, fatigue, loss of appetite, fever, headache, and abdominal pain. The average time period from exposure to symptom onset is 6-7 weeks, whereas the average time period from exposure to seroconversion (the change of a serologic test from negative to positive, indicating the development of antibodies in response to infection or immunization) is 8-9 weeks.

There is no post-exposure treatment to prevent infection by HCV; however, there are treatments once an individual is diagnosed with HCV. Few individuals are able to clear the virus from their blood, which is necessary for recovery. According to the Centers for Disease Control and Prevention (CDC), HCV infection is the most common chronic bloodborne viral infection in the United States.²

Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS)

Human Immunodeficiency Virus (HIV) is the virus that causes Acquired Immunodeficiency Syndrome (AIDS), a disease in which the body's immune system breaks down. HIV is passed from one person to another through blood-to-blood and sexual contact. Blood, semen, breast milk, vaginal fluid, and other body fluids containing blood have been proven to transmit HIV. People with HIV have what is called HIV infection. Most of these people will develop AIDS as a result of the HIV infection.

A positive HIV test result means the person is infected with HIV, but it does not mean that a person has AIDS. An HIV-infected person receives a diagnosis of AIDS after developing one of the CDC-defined AIDS indicator illnesses. An HIV-positive person who has not had any serious illnesses also can receive an AIDS diagnosis on the basis of certain blood tests (CD4+ counts).

One cannot rely on symptoms to know whether or not one is infected with HIV. The only way to determine whether one is infected is to test for HIV infection (e.g., rapid test, EIA). Most people will develop detectable antibodies within 3 months after infection, the average being 25 days. Many people who are infected with HIV do not have any symptoms at all for many years. There is treatment after possible exposure to HIV (chemoprophylaxis) to help reduce the chance of infection as well treatment options available to individuals positively diagnosed with HIV.

Record-Keeping/Confidentiality

Several statutory provisions and department policies establish requirements regarding record keeping and the confidentiality of the information set forth in medical records that are relevant to this provider bulletin.

RCW 51.28.070 states that the information contained within the claim files and records of injured workers maintained by the Department shall be deemed confidential and not open to public inspection. Only individuals with specific authorization or responsibilities related to the worker's claim shall be authorized to inspect such records.

² Centers for Disease Control and Prevention (CDC). *MMWR: Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease*. October 16, 1998, Vol.47, p19.

Under the WISHA Bloodborne Pathogen Standard, WAC 296-62-08001(6)(c)(ii), employers are required, if feasible, to identify the source individual in an exposure incident in order to request their consent for blood testing. However, to ensure the source patient's confidentiality, the Department requests that records sent to the Department for the purposes of a workers' compensation claim file do not identify the source patient.

Attending providers who treat workers are legally obligated to release to the Department or self-insured claims administrator, all information related to an industrial injury or exposure to an occupational disease. RCW 70.24.105(j) specifies that disclosure of confidential information can be made only "for the prompt and accurate evaluation and payment of medical or related claims."

Therefore, as specified in Department policy 1.42, individuals or groups not authorized to handle or determine medical claims payment must obtain a STD release from the worker to receive STD information. Examples include the worker's attorney, ancillary health care providers, the State Fund employer, and employees of the self-insured employer who are not involved in handling and determining medical claim payments.

Additional Resources

- ◆ Centers for Disease Control and Prevention (CDC). *Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease*. **MMWR** 47(RR-19), 1-39, October 16, 1998. <http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/m0055154/entire.htm>
- ◆ Centers for Disease Control and Prevention (CDC). *Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis*. **MMWR** 47 (RR-7), 1-28, May 15, 1998. <http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/m0052722/entire.htm>
- ◆ HIV/AIDS Bureau, Health Resources and Services Administration. *A Guide to the Clinical Care of Women with HIV: 2001*. [Http://hab.hrsa.gov/womencare.htm](http://hab.hrsa.gov/womencare.htm)
- ◆ CDC Website: <http://www.cdc.gov/>
- ◆ CDC National AIDS Hotline: **1-800-342-AIDS**
- ◆ CDC Hepatitis Hotline: **1-888-443-7232**
- ◆ HIV/AIDS Treatment Information Service (ATIS): or <http://www.hivatis.org/> or **1-800-448-0440**
- ◆ Washington State Department of Health- HIV/AIDS Hotline: **1-800-272-AIDS**
- ◆ National AIDS Clearinghouse, Center for Disease Control and Prevention: **1-800-458-5231**
- ◆ National Clinicians' Postexposure HIV Hotline: **1-888-448-4911**
- ◆ Harborview Medical Center, Infectious Disease Program/PEP Clinic: **(206) 751-5100**

- ♦ Washington Industrial Safety and Health Act (WISHA) Services:
Bloodborne Pathogen Standard (WAC 296-62-08001):

<http://www.lni.wa.gov/wisha/p-ts/BBPathogens/>

Needlestick Injury Prevention: <http://www.lni.wa.gov/wisha/p-ts/needlestick/>

For Additional Department of Labor and Industries Information:

The Provider Hot Line @ 1-800-848-0811

The Hot line can help you with:

- Billing questions
- Clarification of Provider Bulletins, fee schedules, department policies, WACs, and RCWs
- Authorizations

Providers can also call the department's **Interactive Voice Response (IVR)** system at 1-800-831-5227 between the hours of 6:00am and 7:00pm weekdays, to obtain automated information regarding the status of a claim, authorized medical procedures, allowed diagnosis, a claim manager's name and phone number, and other claim specific information.

Office of the Medical Director:

For additional information on existing medical coverage decisions or if you have a question about a new emerging technology, device, or off-label use of a drug, contact the Office of the Medical Director at:

Department of Labor and Industries
Office of the Medical Director
P.O. Box 44321
Olympia, WA 98504-4321

For questions about what will be authorized on a specific claim, contact the self-insured employer or State Fund claim manager.

The Office of the Medical Director website (<http://www.lni.wa.gov/omd/>) features:

- Diagnosis and treatment guidelines
- Health links
- Department-sponsored medical publications
- Recent medical coverage decisions

Health Services Analysis Website: <http://www.lni.wa.gov/hsa/>

This website features:

- Provider Bulletins and Provider Updates
- Medical Aid Rules and Fee Schedules
- Provider education opportunities